REMARKS / ARGUMENTS

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claim 5 remains unchanged and claims 1, 3, 4 and 6 have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a method for microbially deactivating items, such as medical, dental, pharmaceutical, veterinary or mortuary instruments and devices, using a liquid microbial deactivation system. Typically, the items to be deactivated are placed within a container that is placed within a deactivation chamber of a reprocessor. Following a deactivation cycle, the deactivated items are manually removed from the container. No matter how carefully the items are removed from the reprocessor, the items are exposed to airborne bio-contaminants in the surrounding atmosphere.

The present invention provides a method of microbially deactivating items in a sealable container. The present invention also provides a method of storing the deactivated items in a location remote from a reprocessor for a prolonged period of time in a sealable container that forms a microbial barrier around the deactivated items. In accordance with present invention, a container for deactivating items and storing the deactivated items therein is provided. The container includes fluid access ports that have a normally closed position and an open position. The fluid access ports are moveable to the open position by contacting the access ports with an actuating means on a reprocessor. When the container is removed from the reprocessor following a deactivation cycle, the fluid access ports move to, i.e., assume, the normally closed position to create a microbial barrier to the entry of any microbial contamination through the access ports. In this manner, the container forms a microbial barrier around the items contained therein. The microbially isolated items can be stored in the container until they are used again.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a method of microbially deactivating items and creating a microbial barrier around the deactivated items as presently set forth in the claims, or the advantages thereof.

In response to the Examiner's rejections, claim 1 has been amended to state that the deactivated items are stored "in a sealable container that forms a microbial barrier around said items." A step of "disengaging" (step f) has been amended to read that the fluid access ports disengage as the container is removed from the reprocessor, causing the access ports to assume a closed position "sealing said container." The sealed container "forming a microbial barrier around" the items contained therein.

Claim 3 has been amended to state that the items in the container are heated "while maintaining said items in a deactivated state."

Claim 4 has been amended to state that the deactivated items are stored "in a sealable container that forms a microbial barrier around said items." A step of "causing"(step f) has been amended to read that the fluid access ports disengage from the activating means, thus "sealing said container, said sealed container forming a microbial barrier around said items."

Claim 6 has been amended to state that the heating of the items occurs "while maintaining said items in a deactivated state."

Claims 4 – 6 stand rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103, as being obvious in view of, U.S. Patent No. 6,919,057 to Halstead et al.

The Examiner stated that "Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having sealing members, a cavity, and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor (abstract), thus engaging the ports,

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed."

Halstead et al. '057 discloses placing an endoscope to be disinfected into a rack and a container located on the rack, as shown in FIG. 2 of the '057 reference. As such, only the head of the endoscope is placed in the container disclosed in Halstead et al. '057. Thus Halstead et al. '057 does not disclose the step of forming "a microbial barrier around" the items in the container.

The Examiner states in step a) that the Halstead et al. '057 discloses "a rack *within* a container."(emphasis added) Halstead et al. '057 discloses that the container "includes an outlet 80 through which a flexible tubular member of the endoscope, such as a light guide connector cord 82 passes (FIG. 7). A light guide connector 84 and its associated cord 82 are then *arranged on a horizontal mesh basket 85* of the cart 12 so that their exterior surfaces are cleaned and disinfected in the reprocessor (FIG. 2)." (column 5, lines 47-53) (emphasis added) The rack disclosed in Halstead et al. '057, item 12, is located *outside* of the container (16). In this respect, only a portion of the item to be deactivated is placed within the container. Thus Halstead et al. '057 does not disclose the step of providing a "sealable container that forms a microbial barrier around said items."

The Examiner also stated that the "ports" disclosed in step a) are engaged in step b) in the Halstead et al. '057 patent. As Applicant understands the Examiner's statement, the port referred to by the Examiner in step a) is item 120 in Halstead et al. '057. Applicant respectfully submits that the port cited by the Examiner in step a), i.e., item 120, does not engage the reprocessor. Item 120 in the Halstead et al. '057 reference is located in outlet port 80, which, as shown in FIGS. 2, 3, 6 and 7, is the port through which the endoscope extends. Halstead et al. '057 discloses that the engagement in step b) occurs when the container and rack are rolled into the reprocessor. Halstead et al. '057 discloses that the "rack 12 is mounted on wheels 270 to roll into and out of the reprocessor on tracks 272 adjacent sides of the chamber 14 (not shown). The hose 162 is connected to the manifold 163 via the outlet 164, for example, with a press fit connection." (column 11, lines 32-35). Thus, the outlet that engages the reprocessor when the container and rack are placed into the reprocessor is outlet 164, not outlet port 80. The ports identified in step a) do not engage the reprocessor in step b). Therefore, Halstead et al. '057 does not disclose the steps of "placing items within a cavity in a sealable container having fluid access

ports therein, said fluid access ports having a normally closed position" *and* "causing said fluid access ports in said container to engage actuating means on said reprocessor."

The Examiner states in step d) that the container in the Halstead et al. '057 reference "would inherently store the items therein until removed." However, the items could not be stored in a container that forms "a microbial barrier" around the items disposed therein because, as discussed above, only a portion of the endoscope is disposed in the container disclosed in Halstead et al. '057. The container in Halstead et al. '057 exposes a portion of the endoscope to microorganisms outside of the container if stored separately from the reprocessor. Thus, Halstead et al. '057 does not teach, suggest, or show a step of "forming a microbial barrier around said items therein."

Claims 5 and 6 depend from claim 4. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 4.

For the foregoing reasons, claims 4 – 6 are not anticipated by Halstead et al. '057 because Halstead et al. '057 discloses placing an endoscope partially within a container and a rack. Halstead et al. '057 does not teach, suggest, or show a method of microbially deactivating items and storing the same in a sealable container forming a microbial barrier around the items. Halstead et al. '057 also does not teach, suggest, or show a fluid access port that both engages a reprocessor *and* forms a microbial barrier around the items within a container when the container is removed from the reprocessor.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead et al. '057. Referring now to claim 1, Halstead et al. '057 does not teach, suggest, or show a step of "causing said fluid access ports to assume said normally closed position to form a microbial barrier." In this regard, as discussed above regarding claim 4, the container disclosed in Halstead et al. '057 is disclosed as only surrounding a portion of the endoscope.

Because Halstead et al. '057 does not teach a fluid access port that is operable to form a microbial barrier, Halstead et al. '057 cannot teach a step of storing the items in a container that forms a microbial barrier around the items.

The Examiner also states that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30)." As Applicant understands the Examiner's statement, Examiner refers to performing a leak test on the *container* disclosed in Halstead et al. '057. As can be appreciated by one skilled in the art, the leak test discussed by Halstead et al. '057 refers to performing a leak test on the *endoscope*. A leak test is typically performed on medical instruments to verify that critical electrical components **within** the endoscope are fluidly sealed from liquid external to the endoscope. A leak test consists of forcing air into a compartment, within the endoscope, wherein the electrical components are located. If the compartment is adequately sealed, the pressurized air will not escape from the compartment and the electrical components therein will not be damaged when the endoscope is submerged in liquid. In order to perform a leak test on an endoscope an operator must make a *physical* connection to the endoscope. The port(s) to which an operator must connect would be similar to the ports shown in FIG. 7 of Halstead et al. '057, items 172, 174, 176 and 178. In this regard, Halstead et al. '057 actually teaches opening the container to gain access to the ports on an endoscope to perform a leak test on the endoscope. Therefore, it would *not* "have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead et al. '057 to assume the closed position" because performing a leak test on an endoscope requires the container to be opened to allow access to the ports on the endoscope therein. Because Halstead et al. '057 teaches opening a container to perform a leak test on the endoscope therein, Halstead et al. '057 cannot teach a step of "storing said container forming a microbial barrier around said deactivated items therein."

In the present application, claim 3 depends from claim 1. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 1.

In summary, the cited reference does not teach, suggest, or show a method for microbially deactivating items and storing the same in a sealable container forming a microbial barrier around said items as claimed in the present application. Halstead et al. '057 does not

teach, suggest, or show a step of disengaging a fluid access port to form a microbial barrier. Further, Halstead et al. '057 does not show a step of storing a container that forms a microbial barrier around the items.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8630US.

Respectfully submitted,

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